

REMARKS

Applicants present this Second Preliminary Amendment in response to the Examiner's Amendment, faxed April 6, 2005 and the Examiner initiated telephone interview of April 8, 2005 with Applicants' representatives Michael Siekman and Marie Aucoin. Applicants have amended the specification as requested by the Examiner. Applicants have amended a typographical error on page 19 of the specification (proteins was corrected to protein). Applicants have added the phrase "which is" to Example 9 as requested by the Examiner. Applicants have replaced the term "CM" with "culture medium" in the paragraph on page 36 as requested by the Examiner. Support for this amendment can be found in the specification on page 8, lines 18-21. Applicants have amended Table 65 and Table 630 to re-number them to Table 9 and Table 40 respectively as requested by the Examiner. Applicants have amended the sequence identifiers in Table 21 to reflect the substitute sequence listing submitted herewith. Applicants have added sequence identifiers to the restriction enzymes PflMI and XcmI as requested by the Examiner. No new matter has been added.

Applicants submit herewith a set of claims which are amended as suggested by the Examiner. The claims have been amended to clarify the claims. Claims 1-42 are cancelled without prejudice or disclaimer. New claims 49-52 are added. No new matter has been added.

Applicants submit herewith a substitute sequence listing. Applicants have amended the sequence listing to include three sequences disclosed in Table 21 which were inadvertently excluded. No new matter has been added.

Summary of Telephone Interview

The Applicants wish to thank Examiner Moore for his courtesy during the telephone interview with Applicant's representatives. During the interview the Examiner raised a potential issue of a Nonstutory Double Patenting Rejection over US Patent No. 5,403,484 ("the '484 patent"). The potential issue referred to claim 26 of the '484 patent and subsequent dependent claims 32, 33, 35, 37, 38, and 42.

Applicants respectfully point out that domination by itself cannot support a double patenting rejection. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on

an invention defined in a narrower or more specific claim in another patent or application (see MPEP § 804 II). Instead the requirements for a nonstatutory double patenting rejection are the same requirements for determining obviousness under 35 U.S.C. § 103. The factors to be considered are:

- (A) Determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness. Id.

The claims presented are not rendered obvious by the claims in the '484 patent for at least the following reasons. The claims in the '484 patent encompass a binding protein produced using phage display, which comprises at least a functional portion of a coat protein of a virus. They make no mention of ITI-D2. Indeed, the '484 patent itself teaches away from the use of ITI-D2 for the development of an inhibitor of human neutrophil elastase. The '484 patent mentions the two Kunitz domains of ITI (see column 153, lines 35-38). Nonetheless, the '484 patent uses ITI-D1 to the exclusion of ITI-D2. Indeed the '484 patent expressly states that one advantage of ITI-D1 is that it lacks affinity for serine proteases related to human neutrophil elastase (see column 154, lines 1-4), specifically "trypsin, chymotrypsin, and plasmin". In contrast to ITI-D1 the '484 patent states, ITI-D2 inhibits "trypsin, chymotrypsin, and plasmin" (see column 153, lines 38-41. Thus the '484 patent expressly states that it used ITI-D1 because it did not have the very same activity possessed by ITI-D2. Therefore the current claims are not rendered obvious by the cited claims of the '484 patent.

CONCLUSION

Applicants believe this amendment puts the claims in condition for allowance. A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance to resolve an remaining issues.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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